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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,889	09/22/2006	Vijaylakshmi Venkateshan	4544-051935	1978

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EXAMINER

SCHUBERG, LAURA J

ART UNIT	PAPER NUMBER
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1657

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,889	Applicant(s) VENKATESHAN ET AL.	
	Examiner LAURA SCHUBERG	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 6-10 are pending and have been examined on their merits.

Claim Objections

Claim 6 is objected to because of the following informalities:

Claim 6 recites the limitation "hepatocytes cells" in line 1. This is grammatically incorrect.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 -10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khan et al (Indian Journal of Gastroenterology 2002) in view of Washizu et al (Tissue Engineering, 2001) and Montesissa et al (Veterinary Research Communications, 1996).

Claim 6 is drawn to a process for characterization of hepatocytes in goat comprising: isolating goat hepatocytes and characterizing the isolated hepatocytes by biochemical and molecular techniques to demonstrate the hepatic functions.

Dependent claims include wherein the isolation is carried out in a laminar flow unit under aseptic conditions (claim 7), wherein collagenase digestion is used to perform the isolation of a single cell suspension (claim 8) wherein the isolated cells are hepatocytes which demonstrate the hepatic functions (claim 9) and wherein the hepatic functions comprise ureagenesis, detoxification and albumin synthesis (claim 10).

Khan et al teach the characterization of isolated goat hepatocytes for the development of a bioartificial liver. Goat hepatocytes are isolated using a collagenase

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digestion and manipulated to disperse hepatocytes completely which would give a single cell suspension (page 55 Methods). Detoxification and ureagenesis of the isolated hepatocytes are observed and analyzed by biochemical techniques (page 56 Results).

Khan et al do not teach using molecular techniques to analyze the hepatic functions of the cells or the specific use of aseptic conditions and a laminar flow hood for the isolation of the cells. Khan et al do not teach wherein the hepatic functions observed include albumin synthesis.

Washizu et al teach the use of xenogeneic hepatocytes as a component of bioartificial livers (page 692 2nd paragraph). Important liver-specific functions include the synthesis of albumin and detoxification functions such as ureagenesis. In order for treatment using bioartificial liver assist systems to become clinically feasible, it is essential that hepatocytes in the device express high and stable levels of liver-specific functions (page 691, Introduction). Albumin concentration is measured using molecular techniques (page 694, Measurement of synthetic functions).

One of ordinary skill in the art would have been motivated to use molecular techniques in the method of Khan et al to measure the albumin concentration because Washizu et al teach that this is an important liver-specific function and that it is essential that hepatocytes in the device express high and stable levels of liver-specific functions (page 691, Introduction). One of ordinary skill in the art would have had a reasonable expectation of success because Washizu et al teach that xenogeneic sources for

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hepatocytes are a viable alternative to human hepatocytes in bioartificial livers and both Khan et al and Washizu et al are drawn to the production and use of a bioartificial liver.

Montesissa et al teach the isolation of goat hepatocytes for the analysis of hepatic functions and use sterile (aseptic) conditions and a laminar air cabinet during the collagenase digestion of the goat liver tissue (page 451-452 Isolation of hepatocytes).

One of ordinary skill in the art would have been motivated to use sterile techniques and a laminar flow hood during the isolation of the hepatocytes in the method of Khan et al because this would have allowed the cells to be collected without contamination and because Montesissa et al teach that this is a suitable manner in which to isolate cells. One of ordinary skill in the art would have had a reasonable expectation of success because Montesissa et al were also isolating goat hepatocytes for the analysis of hepatic functions.

Therefore the combined teachings of Khan et al, Washizu et al and Montesissa et al render obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Schuberg/
Examiner
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